HFEA Executive Licensing Panel Meeting

31 October 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0019 – (Aberdeen Fertility Centre) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	Committee Secretary:
Paula Robinson – Head of Business Planning (Chair) David Moysen – Head of IT Matthew Watts – Regulatory Policy Manager	Dee Knoyle

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a medium-sized centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1992 and is on a four-year licence due to expire on 31 January 2015.

4. The Panel noted that in the 12 months to 30 June 2014, the centre provided 821 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period April 2013 to March 2014 show that the centre's success rates were in line with national averages.

6. The Panel noted that in 2013 the centre performed 17 cycles of IUI with four pregnancies. This equates to a 24% success rate. However, due to a technical error, the centre did not submit its data within the timeframe specified and therefore the results were not included in the statistical analysis.

7. Between 1 May 2013 and 30 April 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The Panel noted that at the time of the inspection on 5 and 6 August 2014, the Inspectorate identified three major and four other areas of non-compliance. The Panel noted that the Person Responsible (PR) has committed to fully implementing the outstanding recommendations with the prescribed timescales.

9. The Panel noted the Inspectorate's recommendation to renew the centre's treatment and storage licence without any additional conditions for a period of four years.

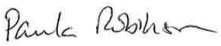
Decision

10. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

11. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

12. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

13. The Panel endorsed the Inspectorate's recommendation to renew the centre's treatment and storage licence without any additional conditions for a period of four years. The Panel also encouraged the PR to ensure efficient data submissions to the HFEA.



Signed: Date: 6 November 2014

Paula Robinson (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 5 and 6 August 2014

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Janet Kirkland MacHattie, Sara Parlett, Chris Hall, Neil McComb, Anjeli Kara (observing).

Date of Executive License Panel: 31 October 2014.

Centre name	Aberdeen Fertility Centre
Centre number	0019
Licence number	L/0019/14/c
Centre address	Department of Obstetrics & Gynaecology, Aberdeen Maternity Hospital, Foresterhill, Aberdeen, AB25 2ZD, UK
Person Responsible	Dr Abha Maheshwari
Licence Holder	Ms Alison McTavish
Date licence issued	1 February 2011
Licence expiry date	31 January 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Aberdeen Fertility Centre has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 821 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2014. In relation to activity levels this is a medium sized centre.

Other licensed activities of the centre include storage of gametes and embryos. A variation of the licence to reflect a change of Person Responsible (PR) was approved by the ELP on 10 August 2012.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period April 2013 - March 2014 show the centre's success rates are in line with national averages.

In 2013 the centre performed 17 cycles of IUI with four pregnancies. This equates to a 24% success rate. However, the centre did not submit its data within the timeframe specified and therefore the results were not included in the statistical analysis of the sector's results. This reporting failure was due to a technical error made by the centre during submission and it is considered disproportionate to make a recommendation in relation to this data submission anomaly.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 May 2013 and 30 April 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision:

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major and four 'other' areas of non-compliance which have resulted in the following recommendations:

Since the inspection visit, the following recommendations have been fully implemented:

Major areas of non compliance:

- the PR should ensure that serious adverse events are reported to the HFEA;

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- the PR should ensure that the HFEA is informed of the receipt of imported samples of donor sperm;
- the PR should ensure that information provided to patients regarding the use of their embryos in training is compliant with Standard Licence Condition (SLC) requirements;

'Other' areas that requires improvement:

- the PR should formalise the validation of all critical equipment in use at the centre;
- the PR should ensure that where possible all equipment/materials used at the centre are CE marked;
- the PR should ensure that standard operating procedures (SOPs) are in place for all activities authorised by their licence;
- the PR should ensure that patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms.

Recommendation to the Executive Licensing Panel:

The centre has no critical areas of concern but does have three major areas of concern.

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.
The inspection team recommends the renewal of the centre's treatment and storage licence for a period of 4 years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; Directions 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre does not have any satellite/transport arrangements.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important

to assure the quality of the services provided.

Infection control; medicines management; pre-operative assessment and the surgical pathway
Due to the limited availability of inspectors and that these areas of practice remain under the regulatory remit of Healthcare Improvement Scotland, compliance with guidance relevant to these practices was not reviewed on this inspection.

Multiple births (Guidance note 7; Directions 0003)
The single biggest risk of fertility treatment is a multiple pregnancy.
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are broadly compliant with HFEA requirements that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for import and export of gametes and embryos are partially compliant with HFEA requirements.
See obligations and reporting requirements guidance note 32.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- to identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not have any transport or satellite arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. Equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is broadly compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are broadly compliant with HFEA requirements. The centre reports adverse incidents (including serious adverse events and reactions) to the HFEA, with one exception detailed below. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services they offer.

What the centre could do better

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The dry shipper available for the transport of gametes and embryos has not been

validated (SLC T24).
See recommendation 4

Quality management system (QMS) (Guidance note 23)
At the time of the inspection the centre did not have a documented SOP to direct the process of donor recruitment, assessment and screening (SLC T33(b)).
See recommendation 6

Equipment and materials (Guidance note 26)
The centre has recently moved to a newer, more robust process for validating critical equipment. Newer equipment has been validated using this process to good effect, however some equipment which has been in use for some time at the centre has not been revalidated using this more robust process as yet and therefore could not be considered by the inspection team to have been fully validated although evidence of servicing and regular monitoring was available. The centre provided evidence of a programme of retrospective validation using the new methodology which has been implemented on the basis of risk associated with each piece of equipment (SLC T24).
See recommendation 4

The serological pipettes in use at the centre are not CE marked (SLC T30).
See recommendation 5

Adverse incidents (Guidance note 27)
A review of the centre's incident log carried out on inspection highlighted an incident which had not been reported to the HFEA (SLC T120).
See recommendation 3

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (T1214/8).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements.
The centre has suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
Due to the limited resources available to this inspection team and given that this is considered a low risk area because the Trust remains under the regulatory remit of Healthcare Improvement Scotland, this area of compliance was not reviewed on this inspection.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

The centre does not perform embryo testing and therefore this area of practice is not applicable to this inspection.

What the centre could do better

Not applicable

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors were unable to speak to any patients regarding their experiences. However, 21 patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was predominantly positive with 14 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

It was possible to assess on the basis of this feedback and observations made in the course of the inspection that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent [and prior to consenting to legal parenthood].

Egg sharing arrangements (Guidance note 12; Direction 0001)
The PR is intending to introduce egg share as a treatment option. The PR provided the inspection team with SOPs and patient information which they had prepared. The centre's proposed procedures for egg sharing arrangements were considered to be compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and / or donors are broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

See use of embryos for training staff (Guidance note 22).

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Five discrepancies were found between 24 completed patient/partner and donor disclosure consents in patient and donor files and the related consent data that the centre has submitted to the HFEA register (Directions 0005).
See recommendation 7.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are partially compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better

Use of embryos for training staff (Guidance note 22)
At the time of the inspection the centre did not have a documented SOP for the use of embryos in training (SLC T33(b)).
See recommendation 6

Written information provided to patients regarding the use of their embryos in training does not include the following:

- that the decision to donate will not affect their treatment in any way;
- that they can vary or withdraw their consent up until such times as they are used in training;
- whether any information will be fed back to them (SLC T97).

See recommendation 2

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; Directions 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are partially compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found the quality of data submitted to the HFEA to be good and submissions to be timely.

What the centre could do better

The centre has not informed the HFEA of the receipt of imported samples of donor sperm (General Direction 0006).
See recommendation 1.

Section 3: Monitoring of the centre's performance

Following the interim inspection in October 2012, recommendations for improvement were made in relation to, two areas of major non-compliance and two 'other' areas of non-compliance.

The PR provided information and evidence that all the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

In the twelve month period prior to the inspection the centre has not received any performance alerts in relation to success rates.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre team have not informed the HFEA of the receipt of any imported samples of donor sperm (General Direction 0005).	The PR should with immediate effect ensure that the HFEA is informed of the receipt of imported samples. The PR should liaise with the registry team at the HFEA regarding the reporting of historical imports by 5 November 2014.	We have liaised with Registry staff at HFEA. I can confirm that all GI forms have been submitted to HFEA . This delay was due to in house computer problem. We are merging databases and are hopeful that it will be resolved by October 2014	The inspector is satisfied with the response and encourages the PR to ensure that all centre staff are aware of the reporting requirements to the HFEA. In addition the inspector looks forward to receiving confirmation from the PR that all issues regarding the merging of the database are resolved by 5 November 2014.
2. Written information for patients regarding the use of their embryos in training does not include: • that the decision to donate will not affect their treatment in any way	The PR should ensure that information provided to patients regarding the use of their embryos in training is compliant with SLC T97. The PR should supply the HFEA with a copy of the amended patient	The consent form is now amended to comply with T97. Amended copy is attached.	The consent form submitted for the use of embryos in training staff in freezing techniques includes the information required by SLC T97.

• whether any information will be fed back to them (SLCT97)	information by 5 November 2014		However, embryos are also used for other purposes, for example training staff in embryo manipulation. The written information relevant to these other purposes should also be submitted to the centre's inspector by 5 November 2014.
3. A review of the centre's incident log carried out on inspection highlighted an incident which had not been reported to the HFEA (SLC T120).	The PR has now reported this incident and going forward should ensure that serious adverse events are reported to the HFEA through the incident reporting system.	We apolozize for this. It was felt after team discussion that this will not be reported to HFEA as treatment of couple was not affected. We have made all staff aware that any loss of gametes will need to be reported to PR to be reported to HFEA	The inspector is satisfied with the response. No further action.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. Not all of the critical equipment in use at the centre has been subject to a formal documented retrospective validation. There is a robust validation system now in place and the centre provided evidence of working towards revalidation of all equipment prioritised according to risk. Evidence of routine servicing and monitoring of key equipment was available. In consideration of these factors the inspection team consider it appropriate to classify this non compliance as 'other'. (SLC T24).	The PR should provide a list of all critical equipment including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the HFEA by the 3 October 2014. The PR should provide quarterly updates to the HFEA on progress in completing validation. It is expected that validation will be prioritised on the basis of risk and that validation will be complete by 5 August 2015.	We have robust validation system in place since 2009. All equipment prior to this date do have evidence of regular servicing and monitoring, if it is still in use. The value of retrospective validation is perhaps questionable though we have a plan to retrospectively put in place as much of the validation paperwork as possible. In addition some components of validation are not at all possible retrospectively such as : 1) User requirement specification 2) Installation and operational qualifications 3) Final stage of validation- The performance qualification	The PR's response is acknowledged. It is considered that a formal retrospective validation should be performed for all equipment in use. For example, there was very limited evidence available on inspection of validation of the dry shipper. The PR is still requested to provide a list of critical equipment including the date of validation or the planned date by which a retrospective validation will be completed by 3 November 2014. Further action needed.

		is undertaken for all equipment in use as demonstrated at inspection. We are confident that our present validation procedures are appropriate, safe, proportionate and in line with regulatory requirements.	
5. The serological pipettes in use at the centre are not CE marked. As this was the only item of equipment identified on inspection which was not CE marked where CE marked alternatives are available, it was considered proportionate to categorise this as an 'other' non compliance.	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided to patients. In consideration of this, the PR should provide the HFEA with a list of all medical devices currently in use in the clinic. The list should document the CE mark status of each device and where devices are not CE marked the list should document either the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance within the next year. The list should be submitted to the HFEA by 5 November 2014.	The serological pipettes which we use are made by Sterilin Limited and are in compliance with product and quality requirements as documented in BS EN ISO 9001:2008 Quality System. I have attached a scan of the Certificate of Quality Assurance and Sterility. We aim to source a CE marked alternative. As requested we have compiled a list of CE status of laboratory equipment and alternative to the few items that do not have a CE mark are being sourced.	The inspector is satisfied with the response and encourages the PR to continue the process of ensuring that wherever possible only CE marked medical devices are used in the provision of licensed treatments. It is expected that CE marked consumables, where available, will be in use by 6 August 2015. Further action needed.

6. At the time of the inspection the centre did not have documented SOPs for the following activities: • Donor recruitment assessment and screening • Use of embryos in training (SLC T33(b))	The PR should ensure that SOPs are developed for donor assessment recruitment and screening and for the use of embryos in training. The PR should provide the HFEA with a copy of the relevant SOPs by 5 November 2014.	There is an OP in place (OP-AN-0017) for donor recruitment , assessment and screening for sperm donors . For egg donors we have divided the OP into three: OP-DO-0003; OP-DO-0009 & OP-DO 0019). For Embryo donation OP-DO-0011 is in place). We are in process of making an OP for use of embryos in training.	The inspector is satisfied that SOPs are in place to direct the process for donor assessment recruitment and screening. The inspector looks forward to receiving the SOP for the use of embryos in training by 5 November 2014. Further action needed.
7. Five discrepancies were found between 24 completed patient/partner and donor disclosure consents in patient and donor files and the related consent data on the register (General Direction 0005).	The PR should: • Correct the submissions that have been identified as being incorrect; • Review systems and processes to ensure that, going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms; • Conduct an audit six months after implementing	These discrepancies have been corrected. Relevant staff have been been aware of the need to be vigilant about the recording of these data. This aspect will be audited to ensure compliance. A report of the audit will be submitted by 5th February 2015.	The inspector is satisfied with the response and looks forward to receiving the audit results by 5 February 2015. Further action needed.

	changes to confirm that any changes made to systems and processes are having the desired effect. The PR should provide the HFEA with the audit results by 5 February 2015.		

Reponses from the Person Responsible to this inspection report

We are grateful to the Authority for providing us with useful feedback on our overall performance and are pleased that a positive view of the Centre has been provided.

We note there are very few areas of non-compliance and as described above these issues are being addressed.